REMARKS

This response is submitted in reply to the Office Action from the United States Patent and Trademark Office, dated February 18, 2009 ("the Action"). Claims 1-24, 51-53 and 61-76 are pending in the application.

I. The Allowed/Allowable Claims

Applicant acknowledges, with appreciation, the Examiner's statement that Claims 5 and 14 are allowed and that Claims 72-75 would be allowable if rewritten into independent form including all the limitations of the base claim and any intervening claim. Applicant has amended Claim 72 to incorporate the base claim, Claim 70. Claims 73-75 depend directly or indirectly from Claim 72. Accordingly, Applicant respectfully submits that Claims 72-75 are in condition for allowance.

II. New Grounds of Rejection

The Action has withdrawn the previous allowance of the pending claims in light of a newly cited reference, U.S. Patent No. 6,142,146 to Abrams et al. ("Abrams"). The Action rejects the other claims as being anticipated by or obvious in light of Abrams.

With respect to the anticipation rejection, the Action states that Abrams teaches the claimed vibration signal (citing to col. 6, lines 34-39). Applicant respectfully disagrees.

Abrams proposes a signal that is tuned to the resonant vibratory frequency of the piezoelectric element resonator 90. The cited text states that the piezoelectric element is caused to vibrate at a resonant ultrasonic frequency at "a particular frequency and amplitude" (col. 6, lines 36-38)(emphasis added). Note the singular frequency used for vibration at any one time in the range of about 15 MHz to 100 MHz (col. 6, lines 36-37).

Applicant also believes that as Abrams proposes a vibration signal associated with the harmonic resonance of the vibrator, this is not a non-linear signal. As defined by the pending application, the term "non-linear" means that the applied vibratory action or input signal has an irregular signal shape and/or cycle, typically employing multiple superimposed frequencies, and/or a vibratory frequency line shape that has varying amplitudes (peaks) and peak widths over typical standard intervals (per second, minute, etc.) over time. In contrast to conventional

systems, the non-linear vibratory signal input operates without a fixed single or steady state repeating amplitude at a fixed frequency or cycle. This non-linear vibratory input can, thus, transmit a variable amplitude motion to the dry powder (as either a one, two and/or three-dimensional vibratory motion). In the past, other attempts for fluidization may have used either airflow or vibration with linear frequencies that may cause aggregation. For example, in the past, others have proposed uniform frequency systems (using vibrating orifices, ultrasonic systems, and the like) to generate sinusoidal, square, or other uniform signals.

Applicant agrees that Abrams proposes that the vibration frequency and amplitude may be adjusted from a "pre-calibrated" initial frequency and amplitude that cause the element 90 to vibrate at its resonant frequency when no powder is on means 36 (*e.g.*, a hard shell encasing the vibrator 90, col. 5, lines 61-65). However, Abrams proposes adjusting the frequency and amplitude so that the piezoelectric element 90 will vibrate at its resonance frequency as "maximum transfer of vibratory power from the piezoelectric element to the powder" takes place when the piezoelectric element vibrates at its resonant frequency (col. 7, lines 24-30).

Abrams states that the initial frequency and amplitude is pre-calibrated and supplied to cause the element 90 to vibrate at its resonant frequency when no powder cartridge or powder is on the means 36. The device then "cycles through" different frequencies and amplitudes to select which frequency and amplitude should be used with the dry powder during operation. As the frequency generator 74 "cycles through" the different frequencies and amplitudes, the instantaneous power transfer characteristics of the piezoelectric element 90 are determined for each of the different frequencies and amplitudes by the detector 88, which transfers this information to the peak detector 86. The peak detector 86 analyzes the information and the controller 84 correlates local maxima of power transfer characteristics with the frequencies and amplitudes commanded by the frequency generator 74. *See*, col. 7-col. 8.

Summarized, Abrams proposes a pre-calibrated initial frequency and amplitude to cause the piezoelectric ceramic element to vibrate at its resonant frequency when no powder cartridge or powder is on the means 36 (col. 7, lines 21-25). The device uses a feedback control system 72 with a frequency generator 74 that sweeps or cycles through different frequencies and amplitudes. As the generating means sweeps or cycles through the different frequencies, the controller then determines which frequencies result in local maxima associated with "optimal

power transfer" (col. 7, lines 45 et seq. to col. 8, lines 1-5, and lines 19-24) and one is selected as the operational frequency for vibration. Each transducer can have different resonant frequency characteristics and each inhaler can apparently have custom tuning for operation.

Applicant submits that Abrams is directed to using a frequency tuned to the resonator after the powder is in the inhaler to obtain resonance for "maximum transfer of vibratory power" (col. 26-42) and fails to teach or suggest the use of a carrier frequency modulated by a plurality of different frequencies. Notably, and in contrast, the pending claims are directed at vibratory signals that promote reliable fluidic flow of the dry powder by using powder-specific frequencies. The independent claims are restated in part below for ease of discussion. Applicant notes that some of the pending claims have been amended in a non-narrowing manner to recite that the claims are directed to methods or systems that dispense non-pharmaceutical *or* pharmaceutical dry powder formulations.

Claim 1

"generating a first non-linear vibration input signal, the first non-linear input signal comprising a carrier frequency modulated by a plurality of pre-defined different selected frequencies that correspond to a first non-pharmaceutical or pharmaceutical dry powder formulation."

Claim 51

"means for generating a first non-linear vibration input signal, the first non-linear input signal comprising a carrier frequency modulated by a plurality of different selected frequencies that correspond to flow frequencies in flow characteristics of a first non-pharmaceutical or pharmaceutical dry powder formulation."

Claim 61

"generating a first non-linear vibration input signal, the first non-linear input signal comprising a carrier frequency modulated by a plurality of different selected frequencies that correspond to a first non-pharmaceutical or pharmaceutical dry powder formulation."

Claim 66

"generating a vibratory signal comprising a carrier frequency modulated by a plurality of selected frequencies, wherein the selected frequencies corresponding to identified *a priori* flow characteristic frequencies of a non-pharmaceutical dry powder."

Claim 70

"generating a vibratory signal comprising a carrier frequency modulated by a plurality of selected frequencies, wherein the selected frequencies correspond to identified *a priori* flow characteristic frequencies of a non-pharmaceutical or pharmaceutical dry powder."

Claims 12 and 52

Claims 12 and 52 are restated in their entirety as additional features in these claims were not addressed by the Action and are not taught or suggested by Abrams (those features are emphasized below). Applicant respectfully submits that Claims 12 and 52 are patentable over the cited art for at least the recitation of these additional features.

> 12. A method of flowably dispensing or processing dry powders from a device having a dry powder flow path, comprising:
>
> generating a first non-linear vibration input signal, the first non-linear input signal comprising a plurality of different selected frequencies that correspond to a first non-pharmaceutical or pharmaceutical dry powder formulation; and
>
> applying the first non-linear vibration input signal to a portion of a dry powder flow path while the first dry powder formulation is flowing therethrough,
>
> wherein the input signal is derived from an evaluation of time between avalanches as detected in a mass flow analysis of the dry powder formulation.

> 52. An apparatus for processing, dispensing and/or expelling dry powders, comprising:
>
> an elongate flow channel having a width, length, and depth, the flow channel having axially spaced apart inlet and outlet ports, wherein the elongate flow channel is configured to extend in an angular orientation of between about 10-75 degrees relative to the axial direction of flow;
>
> a flexible piezoelectric layer configured to overlie the flow channel so that, in operation, the piezoelectric layer is able to flex upwardly away from the lowermost portion of the underlying flow channel;
>
> a quantity of non-pharmaceutical or pharmaceutical dry powder positioned in the flow channel; and

> a signal generator operatively associated with the piezoelectric layer, wherein, in operation, the signal generator is configured to output a vibratory signal comprising a carrier frequency modulated by a plurality of selected dry powder flow characteristic frequencies for flexing the piezoelectric layer which vibrates the dry powder in the elongate flow channel.

Applicant respectfully submits that not only does Abram fail to teach or suggest the claimed signal recited in the pending claims, Abrams teaches away from the claimed signal as Abrams tunes the element 90 to resonance to obtain maximum transfer of vibratory power with a narrow range (and believed to be a single frequency) aimed at generating harmonic resonance of the vibrator.

Applicant also submits that Abrams teaches away from the claimed invention because the use of a frequency to induce resonant operation of the transducer or vibrator as the energy source would be limited to a very narrow frequency instead of the broad range of frequencies recited by Claims 17, 19, 20, 63-65, 68, 69 determined from the characterization of the dry powder.

Accordingly, Applicant respectfully submits that the pending claims are patentable over Abrams.

Claims 3-4, 6, 8-9, 11, 76

The Action alleges that the subject matter in these claims are obvious because it has been held that discovering optimum or workable ranges involves only routine skill. Applicant respectfully disagrees. Embodiments of the invention are directed at dispensing small amounts of dry powders. It has been problematic to reliably dispense repeatable amounts of dry powder, particularly small amounts. Clearly, not only are the "general conditions" of the claims not taught by the prior art, these features are not merely related to a "workable range". *See* below for additional discussion with respect to experimental data.

Claims 19-20, 68-69

The Action concedes that Abrams fails to teach that the non-linear signal comprises frequencies in the range of between about 10 Hz to 1000 kHz and the kHz range frequencies of

Claim 20 (Action, p. 4). However, the Action alleges that it would have been obvious to modify the signal of Abrams with these frequencies as "it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (Action, p. 4, citing MPEP 2144.05). Applicant respectfully disagrees.

Not only does Abrams not disclose the general conditions of the claim, Abrams teaches away from the use of non-ultrasonic frequencies to avoid noise (*see*, col. 6, lines 45-48). Again, Abrams is directed to using a vibration frequency and amplitude tuned to the resonance frequency of the vibrator 90. While Abrams does teach the use of a frequency for vibrating the powder, the signal is very different from the claimed subject matter. The cited MPEP section is directed to an overlap of ranges or a variation of certain established parameters, such as concentration or temperature. However, embodiments of the invention, instead of using a frequency based on the harmonic resonance of the vibrator to maximize power output of the piezoelectric element, employ a relatively complex vibratory signal with a carrier frequency modulated with a plurality of selected frequencies to promote fluidization of the dry powder. Applicant respectfully submits that the claims are patentable over the cited art.

Claims 63-65

The Action concedes that Abrams fail to teach the number of superpositioned frequencies as recited in Claims 63-65 (and Claim 7). However, the Action alleges that these claims are obvious "since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art." (Action, p. 4-5, citing MPEP 2144.04). Applicant respectfully disagrees.

The cited MPEP section describes a device that uses a water seal with ribs instead of a "plus" shape seal. First, Applicant submits that the claimed features are not mere duplication of working parts of a device. Indeed, the use of several frequencies versus a single frequency tuned to a resonance would appear to dampen the response associated the harmonic resonance and result in less effective power transfer which is sought by Abrams. However, the claimed vibratory signal is directed to the powder formulation rather than the vibrator itself. The selected frequencies are not mere duplication of "essential working parts."

Notably, the affected claims are not directed to just any modification of vibratory frequency, but rather to frequencies based on the powder being dispensed which promotes more reliable fluidization.

Claim 24

Applicant submits that Abrams fails to teach or suggest that high-frequency motion is imparted onto a hopper in the flow path with the outer bounds of the motion being small as recited by Claim 24.

III. Experimental Data

Applicant submits that section 2144.04 of the MPEP states that if the Applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection. Section 2144.05 of the MPEP also states that the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.

As noted above, the claimed subject matter is not merely duplicating working parts of a device, it is are providing novel vibratory signals that promote dry powder fluidization. Applicant submits that the claimed carrier frequency with the modulating frequencies provide improved fluidity of flow for dry powders, and the vibratory signal and frequencies provide new and unexpected results in promoting fluidization of the dry powder.

As previously submitted by Applicant in a response filed August 30, 2008, Dr. Timothy M. Crowder (one of the inventors of the pending application) discussed in a publication experimental results he found for the claimed vibratory signal. See, *Precision powder metering utilizing fundamental powder flow characteristics*, Powder Technology 173 (2007) 217-223. A copy of this publication is attached with this response for the Examiner's ease of reference. This article describes experimental results using vibration frequencies calculated from physical characterization of the dry powders that indicate that the vibratory signal with these frequencies "had a significant influence on the reproducibility of metering". (Abstract). *See also*, Figures 5 and 6 of this article provided hereinbelow for ease of reference, which demonstrate flow filling data comparing sinusoidal to powder specific vibration.

Figure 5

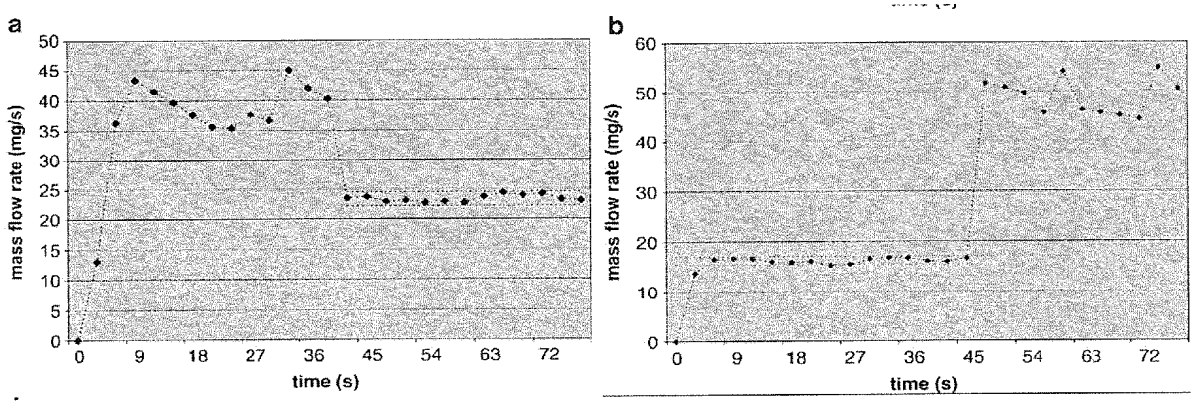
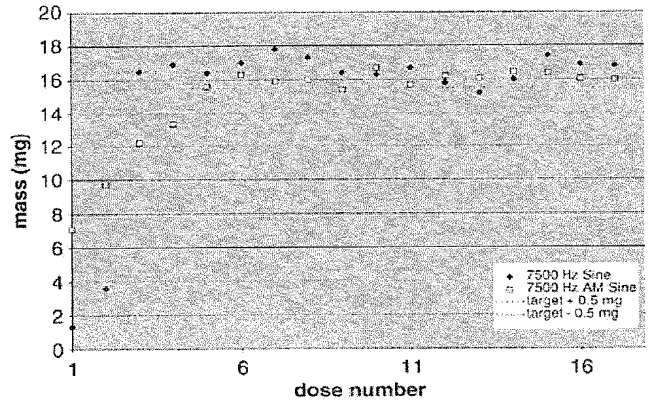


Figure 6



Thus, Applicant respectfully submits that the claimed vibratory signal is nonobvious over prior art vibrations and clearly provides a more uniform fluidic flow, which can improve filling processes/systems.

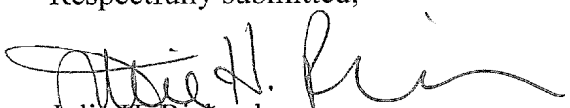
Applicant directs the Examiner's attention to two recent decisions by the BPAI that have overturned an Examiner's obviousness rejections. In one case the BPAI stated that the Examiner used the unwitting application of hindsight, which is inappropriate. *Ex Parte So and Thomas*, BPAI 2007-3967 (Jan. 4, 2008). In another illustrative and recent case before the BPAI, an Examiner alleged that it would have been obvious to one of ordinary skill to optimize workable ranges of a claim. The BPAI reversed the Examiner, pointing out that optimization of a known result-effective variable is generally obvious only when it is reasonably expected that an improvement will arise in that range. *See*, *Ex parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900 (December 18, 2007) (emphasis added). Applicant respectfully submits that the

Action is incorrect when it alleges that the claims with the signal with the frequencies would have been obvious based on the teachings of the invention and alleging "mere optimization" of ranges. Applicant submits that such an analysis employs "unwitting" hindsight.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

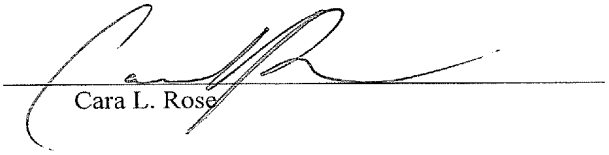


Julie H. Richardson
Registration No.: 40,142

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on May 1, 2009.

Signature: 

Cara L. Rose